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Comparative evaluation of retrograde intrarenal surgery using ureteral access sheath and fluoroscopy: a retrospective analysis on kidney stone treatment

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ABSTRACT

Aims: This study aimed to investigate the outcomes of retrograde intrarenal surgery (RIRS) with and without the utilization of ureteral access sheath (UAS) and fluoroscopy for treating kidney stones and its implications on postoperative complications.

Methods: Employing a retrospective design, we analyzed the records of 314 patients subjected to RIRS due to kidney stones. Patients were categorized into two groups based on the application of fluoroscopy and UAS (Group 1) versus non-application (Group 2). Various metrics, including stone-free rates, residual stone rates, and postoperative complications, were compared between the groups.

Results: The results showed no significant differences between the two groups regarding patient age, stone size, and several demographic parameters. However, there was a considerable reduction in operation duration in Group 2 (20.96±5.97 minutes) compared to Group 1 (26.15±5.41 minutes), where UAS and fluoroscopy were applied, with p=0.001. Furthermore, post-treatment results highlighted a decline in residual stone rates and an enhancement in stone-free rates, though differences between groups were not significant. The incidence of postoperative complications, like fever, urinary tract infections, and ureteral stenosis, was assessed, revealing no differences between the two groups.

Conclusion: The application of RIRS without UAS and fluoroscopy appears to be a promising approach to treating kidney stones, offering similar outcomes regarding stone removal efficacy and postoperative complications compared to the traditional method with UAS and fluoroscopy. This research emphasizes the potential of a less invasive method, warranting further studies to understand its broad implications.

Keywords: Retrograde intrarenal surgery, kidney stone, ureteral access sheath, fluoroscopy

INTRODUCTION

Endourological advances in recent years have ushered in transformative changes in the management and treatment paradigms for renal calculi.[1] The evolution of ureteroscopy tools and state-of-the-art laser technologies has elevated retrograde intrarenal surgery (RIRS) as a predominant therapeutic choice for renal stones.[2] Current literature underscores the efficacy and reliability of RIRS, demonstrating its minimal invasiveness, high success ratios, and remarkably infrequent occurrences of significant postoperative complications.[3,4]

The widespread adoption of RIRS across numerous medical institutions can be attributed to its innate non-invasive nature, complemented by an impressive success trajectory.[5] A prototypical RIRS procedure entails placing a ureteral access sheath (UAS) under fluoroscopic guidance, ensuring renal accessibility via a flexible ureterorenoscope (fURS), and executing lithotripsy utilizing a holmium laser.[6,7] Nevertheless, the utilization of UAS is not devoid of potential risks.[8] Clinical outcomes have reported complications, such as ureteral wall abrasions, ischemic insults to the ureteral wall, and even the rare yet severe ureteral avulsion.[9]

A consequential concern emerging from the protracted use of fluoroscopy pertains to the lurking genetic mutation threats, potentially precipitating oncogenic transformations in patients and the attending medical personnel.[10] While existing literature delves into the comparative surgical outcomes of exclusive UAS or fluoroscopy usage against non-usage protocols, a conspicuous gap remains.[11] Juxtaposed surgical procedures incorporating both UAS and fluoroscopy against those devoid of both modalities were areas with limited research. Our research aims to discern the

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necessity of employing both UAS and fluoroscopy in RIRS, thus adding a perspective and novel contribution to the endourological discourse.

METHODS

The study was carried out with the permission of the İstinye University Clinical Researches Ethics Committee (Date: 26.05.2021, Decision 2/2021.K-32). All procedures were carried out under the ethical rules and the principles of the Declaration of Helsinki.

Study Design

We performed a retrospective assessment, poring over the records of patients who underwent RIRS for renal calculi treatment. All these surgical interventions were orchestrated under the expertise of a singular surgeon skilled in RIRS. Out of the pool, 314 patients conformed to our stringent inclusion criteria and were ushered into the study.

Patient Selection

Patients eligible for the study had renal calculi with a diameter less than 2 cm or those greater than 2 cm but were deemed unfit for Percutaneous Nephrolithotomy (PNL). Furthermore, only individuals aged over 18 years were considered. On the other side of the spectrum, those excluded from the study were those with stones larger than 2 cm that was compatible with PNL, those under 18 years, cases with concurrent ureteral stones, those with detected renal anomalies like Bifid pelvis, calyceal diverticulum, horseshoe kidney, ectopic kidney, duplicated system, and those who underwent a non-lithotripsy surgical procedure with RIRS, such as Endopyelotomy.

Grouping and Measurements

The cohort was bifurcated into two distinct segments for analytical ease. The first ensemble, Group 1, encapsulated patients subject to fluoroscopy and UAS techniques. Conversely, Group 2 pooled patients who were spared these procedures. The dimensional attributes of the stones were ascertained via a trifecta of plain radiography, ultrasonography (USG), and low-dose CT, with the calculative methodologies aligned with the protocols stipulated by the European Urology Guideline. In both groups, an initial entry was made with rigid URS, advancing up to the ureteropelvic junction to check for any ureter pathology or the presence of a stone, after which either UAS or flexible URS was deployed. We meticulously cataloged a plethora of metrics ranging from demographic data, stone characteristics such as its dimensions and locational attributes, the duration of the operation, the span under fluoroscopy, the length of the hospital sojourn, the CT-determined value of the stone, the stone clearance rate, and the incidence of residual stones. In addition, we kept a vigilant tab on postoperative complications, categorizing them in alignment with the nuanced Dindo-Clavien classification. All operations routinely utilized UAS and fluoroscopy; however, based on subsequent observations that the procedural outcomes were comparable irrespective of UAS usage, my approach evolved to primarily exclude UAS, with fluoroscopy being reserved exclusively for cases necessitating UAS placement.

Preoperative and Postoperative Assessments

In the run-up to the surgical endeavor, a comprehensive urinalysis and urine culture were deemed mandatory for all subjects. Patients manifesting signs of urinary infections were earmarked for a preliminary bout of antibiotic therapy. Once cleared, the surgical intervention was given the green light. Postoperative stone evaluations employed an amalgam of direct urinary system radiography and ultrasonography. A month post the surgical foray, these parameters were again brought under the scanner via CT, followed by an extended vigil spanning two years to monitor any lurking complications.

Surgical protocol

Each surgery was prefaced with 1g of ceftriaxone IV administration, and the operations were executed under the aegis of spinal anesthesia. The surgical modus operandi for both Group 1 and Group 2 bore subtle distinctions, detailed as follows: In Group 1, the UAS technique was harnessed along with the c-arm fluoroscopy device. After this, the stone was accessed with fURS, followed by a holmium laser fragmentation. For Group 2, a similar preliminary inspection was conducted using a rigid ureteroscope. The stone location was mapped using the preoperative CT, allowing for direct observation and access. Stones were fragmented using a holmium laser (Quanta Litho® 35 w Milan, İtaly 2015) in dusting or hard stone mode (0.8- 1.2 joules, 8-12 Hz).

Statistical analysis

The statistical analysis of the study was done by SPSS (IBM Corp., Armonk, NY, USA) v25. We employed the Shapiro-Wilk test to assess the distribution patterns of our numerical data. This allowed us to determine whether our data conformed to the normal distribution or deviated from it. We utilized the Mann-Whitney U test for datasets that did not adhere to a normal distribution, as it is specifically tailored for such situations. We resorted to the Pearson chi-square and Fisher's Exact tests for our categorical data, which includes data types typically organized into distinct categories or groups. These tests are instrumental in

determining relationships or associations between categorical variables. In our analysis, a p-value (probability value) less than 0.05 was taken as the threshold for statistical significance. Furthermore, to ensure the reliability and precision of our findings, we operated within a 95% confidence interval.

RESULTS

There was no difference between the groups in terms of patient age and the stone size; the data were found to be 39.96±10.44 years, 17.98±2,02 mm in group 1, and 38.67±11.12 years, 17.53±2,47 mm in group 2, respectively. Demographic data were examined in Table 1, and no difference was found between the groups according to the gender distribution, CT value of stones (Hounsfield units), the location, and the opacity of stones. No difference was observed in the previous stone surgery, the Extracorporeal Shock Wave Lithotripsy (ESWL), and the preop DJ stent (Table 1).

Table 1. Demographic data of the patients

Parameters	Group 1 (n=165)	Group 2 (n=149)	P value
Age (years)(SD)	39.96±10.44	38.6±11.12	0.33
Gender n (%)			
Female	81 (49.09%)	76(51%)	0.77
Male	84 (50.9%)	73(49%)	
Stone size (mm) (SD)	17.98±4.15	17.53±4.63	0.22
Hounsfield Units of Stone	913.87±238.24	895.55±237.3	0.32
Location of Stones n (%)			
Upper calyx and middle calyx	20 (12.12%)	17 (11.4%)	0.93
Pelvis	113 (68.48%)	104 (69.7%)	
Lower calyx	32 (19.4%)	28 (18.9%)	
Opacity of Stones n (%)			
Opaque	156 (94.55%)	137 (92%)	0.35
Non-opaque	9 (5.45%)	12 (8%)	
History of surgery n (%)	24 (14.54%)	19 (12%)	0.66
History of ESWL n (%)	43 (26.06%)	37 (24.8%)	0.82
Preoperative DJ presence n (%)	61 (36.96%)	52 (34.89%)	0.43

Group 1: Cases with Fluoroscopy and Ureteral Access Sheath
Group 2: Cases without Fluoroscopy and Ureteral Access Sheath
n: number of the patients, BMI: body mass index, SD: standart deviation, * p<0.05 value was accepted as significant

When we look at the postoperative first-day clinical results, residue, and stone-free rates were 35.15% and 64.84% in the patients in Group 1. These rates were 28.85% and 71.14% in Group 2 (p=0.15 and p=0.7). Residual stone rates decreased from 35.15% to 23.63% in Group 1 and 28.85% to 17.44% in Group 2 one month after the procedure (p=0.123). Stone-free rates increased from 64.84% to 76.36% in Group 1 and from 71.14% to 82.55% in Group 2. (p=0.17). No s rate was changed between groups in the postoperative first month (p=0.17) (Table 2).

Table 2. Comparison of the postoperative first-day and first-month clinical results between the groups

Parameters	Group 1 (n=165)	Group 2 (n=149)	P value
Residue stone n (%)	58 (35.15%)	43 (28.85%)	0.15
Stone free n (%)	107 (64.84%)	106 (71.14%)	0.7
Parameters (1st Month)			
Residue stone n (%)	39 (23.63%)	26 (17.44%)	0.123
Stone free n (%)	126 (76.36%)	123 (82.55%)	0.17

Group 1: Cases with Fluoroscopy and Ureteral Access Sheath
Group 2: Cases without Fluoroscopy and Ureteral Access Sheath
n: number of patients. * p<0.05 value was accepted as significant

The operation duration was 26.15±5.41 minutes in Group 1 (where the ureteral access sheath and fluoroscopy were used), and the use of fluoroscopy was more extended with 58.23 ± 24.11 seconds; this duration was 20.96±5.97 minutes in Group 2, where they were not used (p=0.001) (Table 3).

There was no difference between the groups in terms of postoperative hospital stay (p=0.09) and DJ stent implantations (p=0.43) (Table 3).

Table 3. Comparison of intraoperative and postoperative data

Parameters	Group 1 (n=165)	Group 2 (n=149)	P value
Operation Duration (min)	26.15±5.41	20.96±5.97	0.001
Fluoroscopy Duration (sec)	58.23±24.11	0	0.001
Hospital Stay Duration (days)	0.98±0.23	1.03±0.2	0.09
The Presence of Postoperative DJ Stent			0.43
Yes	46 (27.87%)	41 (27.51%)	
No	119 (72.12%)	108 (72.48%)	
Ureteral stenosis			0.125
Yes	4 (2%)	0 (0.0%)	
No	160 (98%)	149 (100%)	

Group 1: Cases with Fluoroscopy and Ureteral Access Sheath
Group 2: Cases without Fluoroscopy and Ureteral Access Sheath
Sec: Seconds, Min: Minute, n: number of the patients

Postoperative complications are shown in Table 4 following the modified clavien classification. Fever requiring postoperative antipyretic treatment was observed in 21 (12.72%) patients in Group 1 and 11 (7.3%) patients in Group 2 (p=0.12). Urinary tract infections were detected in 12 (7.27%) patients in Group 1 and 7 (4.6%) patients in Group 2 (p=0.35), and they were treated with appropriate antibiotics. Steinstrasse was detected in three (1.8%) of the patients in Group 1 and four (2.6%) of the patients in Group 2, and the patients were treated with rigid ureterorenoscopy (p=0.71). Ureteral stenosis developed in 4 patients in group 1 postoperatively, one of them was treated with a DJ stent, and when the stenosis did not improve with the DJ stent, the patients were treated with open ureteroureterostomy (p=0.25). In Group 1, urosepsis was detected in one (0.6%) of the patients, and they were treated with appropriate antibiotics and DJ stent implantation (p=1) (Table 4).

Table 4. Comparison of complications of the groups according to Clavien classification

Grades	Complication	Group 1	Group 2	P value
Grade 1	Fever requiring antipyretics	21(12.72%)	11 (7.3%)	0.12
Grade 2	Urinary system infections	12(7.27%)	7(4.6%)	0.35
Grade 3a		0	0	1.0
Grade 3b	Open ureteroureterostomy due to ureteral stenosis	3 (1.8%)	0	0.25
	Rigid ureterorenoscopy due to steinstrasse	3 (1.8%)	4 (2.6%)	0.71
Grade 4a		0	0	1.0
Grade 4b	Urosepsis	1 (0.6%)	0	1.0
Grade 5		0	0	1.0

Group 1: Cases with Fluoroscopy and Ureteral Access Sheath
Group 2: Cases without Fluoroscopy and Ureteral Access Sheath

DISCUSSION

The landscape of urological interventions, particularly RIRS, is replete with advancements in technique and technology, promising more effective and safer surgeries. While commonplace, integration of tools like UAS and fluoroscopy often goes unchallenged, potentially leading us to overlook potential complications or over-reliance. The present research explores the nuanced intricacies of using UAS and fluoroscopy in RIRS, challenging established norms and setting the stage for more informed clinical choices. With this study, we not only take a step towards enriching the literature on the non-routine use of UAS and fluoroscopy but also stand as the pioneering research examining the effects of both UAS and fluoroscopy on concomitant and non-used drugs.

RIRS, PNL, and ESWL are preferred treatments for stones shorter than 2 cm.[12] The advantages of RIRS are that it is non-invasive, incurring shorter hospital stays, less bleeding, and less parenchymal damage;[13] these have made RIRS a more preferable treatment option than PNL for stones shorter than two cm.[14] In addition to such technological developments as improved image quality and increased mobility in flexible URS, the expanded surgical experience of urologists has made the operations safe and effective without using fluoroscopy and the ureteral access sheath.[7] A prospective study by Lima et al.[15] observed urosepsis in 7 of 8 patients where complications existed related to the use of UAS; pain due to stent was observed in 2 patients in the group without UAS, and there was no difference in complication rates between the groups. Damar et al.[16] found in examining the complication rates with and without the use of UAS that there was no difference between the two groups.

Many publications show that using UAS during RIRS reduces intrarenal pressure, achieving better visibility and minimizing damage to the kidney.[17] When the rates of complications were examined, they were observed to be lower in the UAS group; this was thought to be due to decreased intrarenal pelvic pressure in the UAS group. Our study did not use a basket catheter for stone extraction, so we did not need re-entry in either group. Our SFR rates were similar in both groups, as we turned the stones into dust or millimetric fragments with the painting method. Our stone-free rates in RIRS with and without ureteral access sheath were 88.48 and 82.55% upon one-month follow-up, with no difference observed between the groups. While our study observed no difference in hospital stay duration, surgery duration was shorter in the group where UAS was not used. Similarly, in the studies by Lima et al.,[15] surgery duration was shorter where UAS was not used.

Our data indicates that UAS use prolongs surgery duration and fluoroscopy duration. The reduced operation time in the non-UAS group may be attributable to the time saved during UAS placement and the time often consumed towards the end of the procedure in attempts to extract residual fragments using a basket. Recently, with the development of laser devices, stone-free rates have increased. In a study by Sari et al.,[18] stone-free rates in RIRS using a 20-watt and 30-watt laser device were higher than the stone-free rates in lithotripsy performed in dusting mode with a 30-watt device, although both devices were used at the same power and frequency. Stones are pulverized by the dusting technique or fragmented into such small pieces that they pass through the ureter without requiring extraction. Thus stone-free rates are high in RIRS performed without the access sheath. Our stone-free rates are high despite not performing stone extraction because we turn the stones into dust or millimetric fragments.

In some studies comparing the results of operations performed without fluoroscopy, no significant difference was found in stone-free rate and complication development.[10,19,20] When we compare the patient groups with and without fluoroscopy, our stone-free and complication rates show that we can perform effective surgery without fluoroscopy. Studies in the literature compare surgeries performed with and without the use of fluoroscopy alone, those performed with and without the use of UAS alone, and the results of the surgeries performed without fluoroscopy and UAS. In our standard practice, whenever UAS is employed, fluoroscopy is invariably used in conjunction; conversely, if UAS is not used, fluoroscopy is also omitted, ensuring that neither tool was utilized independently of the other. Unlike previous studies, our study compared a group in which fluoroscopy and UAS were used with a group in which neither was used.

When we compared the group in which fluoroscopy and UAS were used and the group in which neither were used, we found no difference in the rates of stone-free and major complications; we observed a higher rate of minor complications in the group in which UAS was used. We think that stone-free rates may have increased due to the experienced surgeons breaking the stones into smaller pieces and finding and breaking up possible residual stones. A urologist who frequently uses flexible ureterorenoscopy in daily practice should review UAS and fluoroscopy. Our study found that using UAS and fluoroscopy did not significantly affect success and complications. Therefore, it may be necessary to reassess whether using UAS and fluoroscopy is mandatory. Considering that successful results can be obtained without using UAS and fluoroscopy, reducing the use of these methods may be considered. However, it is essential to make an individualized assessment for each patient and situation and to consider clinical experience. However, long-term randomized controlled studies with more patients are required for more precise results.

This research breaks new ground by being the inaugural examination of the combined utilization of UAS and fluoroscopy versus their omission in RIRS surgeries. It robustly underscores the salient point that surgeons with ample experience can potentially sidestep fluoroscopy, hence mitigating associated radiation risks. An innovative approach to pulverizing stones was instrumental in achieving commendable stone-free rates, even without stone extraction. However, certain limitations are palpable. In the group where UAS was not used, periodic water evacuation was performed from within the flexible URS during the procedure to reduce kidney pressure and dust particles, resulting in no observed difference in the patients' pain levels. The groundbreaking nature of this study means there is a dearth of comparable literature to benchmark against. Furthermore, results might be intricately linked to the proficiency of the surgeons involved, raising questions about wider generalizability. The study's methodology, which eschewed using a basket catheter for stone extraction, also necessitates careful consideration. While these challenges are pertinent, it is essential to juxtapose them with the study's inherent strengths, ensuring a well-rounded understanding. As we delve deeper into these specifics, we aim to present readers with a comprehensive view of the advantages and constraints of our research. While the study undeniably propounds the rethinking of routine UAS and fluoroscopy usage in RIRS, it is prudent to acknowledge the pressing need for expansive, longitudinal research to authenticate these preliminary findings further.

CONCLUSION

The study determined similar stone-free and complication rates between groups with and without fluoroscopy and UAS, and the procedure could be performed successfully and reliably in both groups. While patients are protected from complications that may develop due to UAS, proper stone mapping with preoperative CT will eliminate the need for fluoroscopy and protect the operating team and the surgeon from the adverse effects of radiation.

ETHICAL DECLARATIONS

Ethics Committee Approval: The study was carried out with the permission of the İstinye University Clinical Researches Ethics Committee (Date: 26.05.2021, Decision 2/2021.K-32).

Informed Consent: Because the study was designed retrospectively, no written informed consent form was obtained from patients.

Referee Evaluation Process: Externally peer-reviewed.

Conflict of Interest Statement: The authors have no conflicts of interest to declare.

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Author Contributions: All of the authors declare that they have all participated in the design, execution, and analysis of the paper, and that they have approved the final version.

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